DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 3, 2002

Mr. Jason E. Berkes, President
Americaloe, Inc.
2045 Corte Del Nogal
Carlsbad, California 92009

W/L 35-02

Dear Mr. Berkes:

This letter is in reference to the "Seasilver" product manufactured, marketed, and distributed by your firms Americaloe, Inc., Seasilver U.S.A., and Future Fulfillment Corporation, respectively.

Our review of your "Seasilver" product revealed that the labeling for this product bears claims that refer to the cure, mitigation, or prevention of disease. These disease claims cause your "Seasilver" product to be a drug, as defined in Section 201 (g) of the Act. Because we are unaware of any evidence that this product is generally recognized as safe and effective when used as labeled, it also is a new drug as defined under Section 201 (p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

The "Seasilver" product is further misbranded under Section 502(f)(1) of the Act, in that it fails to bear adequate directions for use, and under Section 502(a) of the Act, in that the labeling is false and misleading because it suggests that the product is safe and effective for its intended use. Neither safety nor effectiveness has been shown.

Disease claims made for your "Seasilver" product in the brochure entitled "The Leader in Foundational Health" include:

- "Balance Blood Sugar – Hypoglycemia and Diabetes;"
- "Relief From All Inflammatory Conditions – Arthritis;"

- "Provides Allergy Relief;"
- "Reduce Risk of Heart Disease;"
- "Reduces Risk of Stroke;"
- "Reduces Risk of Cancer."

Disease claims are made for your "Seasilver" product in the promotion booklet entitled "Journey into the World of Foundational Health."

- On page 3, Seasilver is claimed to have the following benefits: "Balance[s] Blood Sugar - Hypoglycemia and Diabetes," provides "Relief From All Inflammatory Conditions - Arthritis/Sports Injuries," "Reduces Risk of Stroke," "Reduces Risk of Heart Disease," and "Reduces Risk of Cancer."
- On page 4, Pau D'Arco, an ingredient in "Seasilver," is claimed to have "anti-bacterial, anti-fungal, anti-viral, anti-parasitic...properties" and is described as "one of the most important anti-tumor agents in the world."
- On page 6, Matrix Aloe Vera is claimed to be an "Anti-Inflammatory - for all types of inflammation, burns and wounds," an "Anti-Diabetic," an "Anti-Bacterial/Anti-Viral/Anti-fungal," and an "Anti-Ulcerogenic

If you intend to market your "Seasilver" product as a dietary supplement, it must meet the definition of a dietary supplement in Section 201(ff) of the Act, and must comply with the applicable food labeling regulations in Title 21 of the Code of Federal Regulations, Part 101 (21 CFR 101). However, even if the product meets the legal definition of a dietary supplement, it may be subject to regulation as a drug based on disease claims in the labeling. Thus, a product that meets the definition of a drug is subject to the legal requirements for a drug even if it is also a dietary supplement. See United States v. Ten Cartons ... Ener-B Vitamin B-12, 72 F.3d 285, 287 (2d Cir. 1995).

Section 403(r)(6) of the Act provides that structure/function claims may be made on the labeling for dietary supplements in certain limited circumstances. The Act prohibits express or implicit claims that a dietary supplement has an effect on a specific disease, or class of diseases, unless FDA has authorized the claims in accordance with applicable health claim regulations, see 21 CFR 101.14 and 101.70, through the new drug approval process, see 21 CFR 314, or through the issuance of an OTC monograph, see 21 CFR 330.

If you correct the identified deficiencies in your labeling and provide only allowable structure/function claims for your "Seasilver" product, the product would still be misbranded as follows:

- The product label does not include the term "dietary supplement" as part of the statement of identity, as required by Sections 403(i)(1) and 403 (s)(2)(B) of the Act and 21 CFR 101.3(g). The word "dietary" may be replaced by the name of the dietary ingredients in the product or an appropriately descriptive term, e.g. "calcium supplement" or "herbal supplement with vitamins."

- The nutrition information required by Section 403(q)(5)(F) of the Act is not presented as a Supplement Facts panel, as required by 21 CFR 101.36.

The above violations are not meant to be an all-inclusive list of deficiencies for your products. It is your responsibility to ensure that all of your products comply with the laws and regulations enforced by FDA. You should take prompt action to correct these serious violations and to prevent their recurrence. Failure to make prompt corrections could result in regulatory action

You should notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the violations noted above, including an explanation of each step taken to prevent the recurrence of similar violations. For corrections that you cannot complete within the fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made, including copies of revised labeling.

Your written reply should be addressed to:

Thomas L. Sawyer, Director of Compliance
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612

Sincerely,

Alonza E. Cruse
District Director